

Study Title

100-Person Human Patch Test with
H-21936 (Test Item)

Laboratory Project ID

Haskell Laboratory Report No. 713-96

Study Completed On

September 30, 1996

Contracting Laboratory

ConTox Limited
3408-50 B Street
Philadelphia, Pennsylvania 19134

Author

David Gabriel

for

E. I. du Pont de Nemours and Company
Haskell Laboratory for Toxicology and Industrial Medicine
Elkton Road, P. O. Box 50
Newark, Delaware 19714

Study Monitor

Gregory S. Ladics

[REDACTED]

Company Sanitized. Does not contain TSCA CBI

GENERAL INFORMATION

Test Material

Material Tested:

[REDACTED]

Physical Form:

Clear Water Liquid

Synonyms:

[REDACTED]

Composition:

[REDACTED]

Stability:

In the absence of visible evidence to the contrary, the test materials were assumed to be stable under the conditions of administration.

Sponsor:

DuPont Specialty Chemicals
E. I. du Pont de Nemours and Company
Wilmington, Delaware

Study Initiated - Completed:

8/14/96 - 9/30/96

In-Life Phase

Initiated - Completed:

8/14/96 - 9/18/96

Company Sanitized. Does not contain TSCA CB.

DUPONT CENTRAL RESEARCH AND DEVELOPMENT
HASKELL LABORATORY FOR TOXICOLOGY
AND INDUSTRIAL MEDICINE

October 8, 1996

[REDACTED]

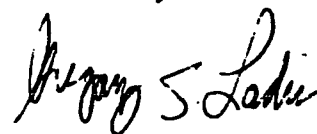
DuPont Specialty Chemicals
Chamber Works

100-Person Human Patch Test with
H-21936 (Test Item)

Attached is a report from ConTox Limited (Project No. 96-8342H). Included in the report are patch test methods, results, and conclusions.

The purpose of this study was to determine the potential of H-21936 to cause irritation or delayed contact hypersensitivity in humans. During the induction and challenge phases of this study, H-21936 (Test Item) produced no adverse skin responses in 100% and 100%, respectively, of those subjects who were active participants.

Based upon the effects observed with the test materials placed repeatedly on the skin during both the induction and challenge phases, H-21936 (Test Item) is not considered to be a skin irritant nor a sensitizing agent under the conditions that prevailed in this study.



Gregory S. Ladics, Ph.D.
Research Toxicologist

ConTox Limited

P.O. Box 368, Fort Washington, Pennsylvania 19034-0368

Telephone: (215) 739-4499

Fax: (215) 423-9210

Project Number: 96-8342H

Testing Facility: ConTox Limited
1358 Lycoming Street
Philadelphia, PA 19124

Sponsor: E.I. du Pont de Nemours & Company
P.O. Box 50, Elkton Road
Newark, DE 19714

Test Article: H-21936

Test Article Description: Pale yellow clear liquid

Test Article Received: 08/08/96

Study Initiated: 08/14/96 **Study Completed:** 09/18/96

Date of Report: 09/30/96

Test: Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Object of Test: To determine the sensitizing properties of the test article.

Reference: The method employed in carrying out this test was similar to that described in "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics" by J.H. Draize and published by the Association of Food and Drug Officials of the United States.

Method of Test: Test Panel: The test involved the application of the test article to the upper arms of a group of 111 volunteer panelists. The panelists ranged from 18 to 70 years of age (see Panelist List, Appendix II). One hundred and five panelists completed the study. Prior to the initiation of the study, all panelists were in good general health and free of any visible skin disease or anomaly in the area to be patched. Each panelist was required to read, understand and sign an informed consent statement.

E.I. du Pont de Nemours & Company - H-21936

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Method of Test:

(continued)

Patch Preparation: The test article was tested as supplied. Approximately 0.2 m² of the test article was applied to a 3/4" diameter cellulose fiber disc (Lintine® disc, Filter Fabrics, Inc., Goshen, IN 46526) which was attached to a strip of 2" Dermicel® hypoallergenic cloth tape (Johnson & Johnson, New Brunswick, NJ 08903). This tape strip was then pressed into place on the upper left arm of each panelist at its designated test site.

Induction Phase: The patch was applied to its designated contact site and remained in place for 24 hours. At the end of this period, the patch was removed and the site was examined for any dermal response. The panelists were then rested for a 24-hour period after which the skin site was again examined. A new patch was then applied to the same site as previously used. Each subsequent application was identical to the first and remained in place 24 hours. This procedure was repeated on Mondays, Wednesdays and Fridays until a series of nine applications had been made. Patch applications made on Friday were removed by the panelists on Saturday. The panelists examined the sites (with assistance if necessary) for any dermal response at the time of removal and again at 48 hours and reported their observations prior to the next application. The same site was used throughout the study.

In the event when one induction application was missed, the panelist was allowed to make it up at the end of the induction patch period. This patch was applied on Wednesday following the last scheduled (ninth) induction application on Monday.

Challenge Phase: After the 9th application, a rest period of approximately 2 weeks elapsed after which a challenge application was applied in the same manner and to the same site as originally patched. A duplicate challenge application was also applied in the same manner to a virgin site (previously untreated) on the other arm. The challenge applications were removed after 24 hours and the sites were examined and graded for signs of irritation or sensitization. A follow-up examination was conducted at 48 hours after the challenge applications (24 hours after patch removal).

The grading scale used throughout both the induction and challenge phases is shown in Appendix III.

Project Number: 96-8342H

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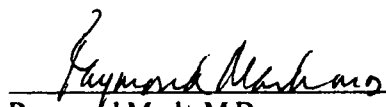
Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Results: Results obtained with the test article (H-21936) are presented in Appendix I. Individual panelist data are presented in Table 1. A summary of the data is presented in Table 2.

Conclusion: From the results obtained with this test panel under the test conditions utilized, the test article does not appear to be a primary skin irritant. The test article does not appear to be a fatiguing agent. The test article does not appear to be a sensitizing agent.

Signatures: Submitted by ConTox Limited:


Frederick Urbach, M.D.
Consultant Dermatologist
Date 10/2/96


Raymond Mark, M.D.
Study Director/Consultant
Date 9/30/96

Approved by:


Karl L. Gabriel, V.M.D., Ph.D.
President
Date 10/2/96

Project Number: 96-8342H

DuPont HLO # 713-96

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

APPENDIX I

RESULTS FOR TEST ARTICLE

Project Number: 96-8342H
 E.I. du Pont de Nemours & Company - H-21936, as supplied.
 Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase												Challenge Phase																					
	1			2			3			4			5			6			7			8			9			10**			Original Site		Virgin Site	
	24	48		24	48		24	48		24	48		24	48		24	48		24	48		24	48		24	48		24	48		24	48		
1	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
2	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
3	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
4	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
5	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
6	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
7	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
8	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
9	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
10	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
11	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
12	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
13	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
14	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
15	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
16	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
17	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
18	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
19	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
20	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
21	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
22	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
23	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
24	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		
25	0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		0	0		

24 = Reading 24 hours after application.

48 = Reading 48 hours after application.

72 = Reading 72 hours after application.

* = Panelist missed the scheduled patch application for personal reasons. Patch was applied on the next scheduled application day, and the patch series extended until 9 induction applications were applied.

** = Make-up patch application.

D = Discontinued from the study for personal reasons.

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ConTox Limited - P.O. Box 368, Fort Washington, Pennsylvania 19034-0368

Project Number: 96-8342H
 F. I. du Pont de Nemours & Company - H-21936, as supplied.
 Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase												Challenge Phase			
	1	2	3	4	5	6	7	8	9	10**	Original Site	Virgin Site	24	48	24	48
26	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
31	0	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D
32	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
34	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
36	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
38	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
44	0	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D
45	0	D	D	D	D	D	D	D	D	D	D	D	D	D	D	D
46	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

24 = Reading 24 hours after application.
 48 = Reading 48 hours after application.
 72 = Reading 72 hours after application.
 * = Panelist missed the scheduled patch application for personal reasons. Panelist was patched on the next scheduled application day, and the patch series extended until 9 induction applications were applied.
 ** = Make-up patch application.
 D = Discontinued from the study for personal reasons.

- n -

Project Number: 96-8342H

E.I. du Pont de Nemours & Company - H-21936, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

DuPont HLO # 713-96

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase												Challenge Phase	
	1	2	3	4	5	6	7	8	9	10**	Original Site	Virgin Site	24	48
51	0	0	0	0	0	0	0	0	0	0	0	0	0	0
52	0	0	0	0	0	0	0	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	0	0	0	0	0	0
54	0	0	0	0	0	0	0	0	0	0	0	0	0	0
55	0	0	0	0	0	0	0	0	0	0	0	0	0	0
56	0	0	0	0	0	0	0	0	0	0	0	0	0	0
57	0	0	0	0	0	0	0	0	0	0	0	0	0	0
58	0	0	0	0	0	0	0	0	0	0	0	0	0	0
59	0	0	0	0	0	0	0	0	0	0	0	0	0	0
60	0	0	0	0	0	0	0	0	0	0	0	0	0	0
61	0	0	0	0	0	0	0	0	0	0	0	0	0	0
62	0	0	0	0	0	0	0	0	0	0	0	0	0	0
63	0	0	0	0	0	0	0	0	0	0	0	0	0	0
64	0	0	0	0	0	0	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0	0	0	0	0	0	0
66	0	0	0	0	0	0	0	0	0	0	0	0	0	0
67	0	0	0	0	0	0	0	0	0	0	0	0	0	0
68	0	0	0	0	0	0	0	0	0	0	0	0	0	0
69	0	0	0	0	0	0	0	0	0	0	0	0	0	0
70	0	0	0	0	0	0	0	0	0	0	0	0	0	0
71	0	0	0	0	0	0	0	0	0	0	0	0	0	0
72	0	0	0	0	0	0	0	0	0	0	0	0	0	0
73	0	0	0	0	0	0	0	0	0	0	0	0	0	0
74	0	0	0	0	0	0	0	0	0	0	0	0	0	0
75	0	0	0	0	0	0	0	0	0	0	0	0	0	0

24 = Reading 24 hours after application.

48 = Reading 48 hours after application.

72 = Reading 72 hours after application.

* = Panelist missed the scheduled patch application for personal reasons. Panelist was patched on the next scheduled application day, and the patch series extended until 9 induction applications were applied.

** = Make-up patch application.

- = Missed reading.

D = Discontinued from the study for personal reasons.

- n -

ConTox Limited, P.O. Box 366, Fort Washington, Pennsylvania 19014-0366

Project Number: 96-8342H

E.I. du Pont de Nemours & Company - H-21936, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

DuPont HLO # 713-96

Table 1 - Individual Panelist Data

Panelist Number	Induction Phase									Challenge Phase			
	1	2	3	4	5	6	7	8	9	10**	Original Site	Virgin Site	
76	24	48	72	24	48	72	24	48	24	48	24	48	0
77	0	0	0	0	0	0	0	0	0	0	0	0	0
78	0	0	0	0	0	0	0	0	0	0	0	0	0
79	0	0	0	0	0	0	0	0	0	0	0	0	0
80	0	0	0	0	0	0	0	0	0	0	0	0	0
81	0	0	0	0	0	0	0	0	0	0	0	0	0
82	0	0	0	0	0	0	0	0	0	0	0	0	0
83	0	0	0	0	0	0	0	0	0	0	0	0	0
84	0	0	0	0	0	0	0	0	0	0	0	0	0
85	0	0	0	0	0	0	0	0	0	0	0	0	0
86	0	0	0	0	0	0	0	0	0	0	0	0	0
87	0	0	0	0	0	0	0	0	0	0	0	0	0
88	0	0	0	0	0	0	0	0	0	0	0	0	0
89	0	0	0	0	0	0	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0	0	0	0	0	0	0
91	0	0	0	0	0	0	0	0	0	0	0	0	0
92	0	0	0	0	0	0	0	0	0	0	0	0	0
93	0	0	0	0	0	0	0	0	0	0	0	0	0
94	0	0	0	0	0	0	0	0	0	0	0	0	0
95	0	0	0	0	0	0	0	0	0	0	0	0	0
96	0	0	0	0	0	0	0	0	0	0	0	0	0
97	0	0	0	0	0	0	0	0	0	0	0	0	0
98	0	0	0	0	0	0	0	0	0	0	0	0	0
99	0	0	0	0	0	0	0	0	0	0	0	0	0
100	0	0	0	0	0	0	0	0	0	0	0	0	0

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72 = Reading 72 hours after application.

* = Panelist missed the scheduled patch application for personal reasons. Panelist was patched on the next scheduled application day, and the patch series extended until 9 induction applications were applied.

** = Make-up patch application.

Project Number: 96-8342H

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

DuPont HLO # 713-96

Table I - Individual Panelist Data

Panelist Number	Induction Phase												Challenge Phase			
	1		2		3		4		5		6		7		8	
	24	48	24	48	24	48	24	48	24	48	24	48	24	48	24	48
101	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
102	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
103	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
104	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
105	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
106	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
107	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
108	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
109	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
110	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
111	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

24 = Reading 24 hours after application.

48 = Reading 48 hours after application.

72 = Reading 72 hours after application.

* = Panelist missed the scheduled patch application for personal reasons. Panelist was patched on the next scheduled application day, and the patch series extended until 9 induction applications were applied.

** = Make-up patch application.

- = Missed reading.

D = Discontinued from the study for personal reasons.

- n -

ConTox Limited - P.O. Box 308, Fort Washington, Pennsylvania 19034-0308

Project Number: 96-8342H

DuPont HLO # 713-96

E.I. du Pont de Nemours & Company - H-21936, as supplied.

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

Table 2 - Summary of Data

	Induction Phase										Challenge Phase			
	1	2	3	4	5	6	7	8	9	10**	Original Site	Virgin Site	24	48
Total	24	48	24	72	24	48	24	48	24	48	24	48	24	48
Panelists:	111	111	111	111	111	111	111	111	111	111	111	111	111	111
Grade														
0	111	108	107	107	107	106	105	104	103	103	105	105	105	105
±	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1+	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2+	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3+	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4+	0	0	0	0	0	0	0	0	0	0	0	0	0	0
-	0	0	0	1	0	0	0	0	0	0	0	0	0	0
*	0	0	0	1	0	0	0	0	0	0	0	0	0	0
D	0	3	3	3	3	4	4	5	6	6	6	6	6	6

24 = Reading 24 hours after application.

48 = Reading 48 hours after application.

72 = Reading 72 hours after application.

* = Panelist missed the scheduled patch application for personal reasons. Panelist was patched on the next scheduled application day, and the patch series extended until 9 induction applications were applied.

** = Make-up patch application.

- = Missed reading.

D = Discontinued from the study for personal reasons.

- n -

ConTOn Limited - P.O. Box 308, Fort Washington, Pennsylvania 19034-0308

Project Number: 96-834211

DuPont HLO # 713-96

E.I. du Pont de Nemours & Company - H-21936

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

APPENDIX II

PANELIST LIST

Project Number: 96-8342H

DuPont HLO # 713-96

E.I. du Pont de Nemours & Company - H-21936

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

PANELIST LIST

<u>Panelist Number</u>	<u>Panelist Initials</u>	<u>Age</u>	<u>Occupation</u>	<u>Allergies</u>
1	M.C.	23	Supervisor	
2'	M.T.	33	Meat packer	
3	C.P.	31	Medical assistant	
4'	B.R.	30	Homemaker	
5	E.T.	41	Dental assistant	
6	B.H.	37	Homemaker	
7	N.R.	36	Homemaker	
8	R.O.	41	Homemaker	Ragweed
9	J.B.	44	Newspaper clerk	Penicillin
10	A.B.	52	Homemaker	Shellfish, seafood
11	L.P.	36	Homemaker	Hayfever
12	M.C.	30	Homemaker	
13	H.D.	53	Homemaker	
14	B.B.	29	Homemaker	
15	A.D.	30	Salesperson	
16	C.M.	36	Salesperson	
17	K.D.	49	Homemaker	
18	C.M.	26	Homemaker	
19	D.P.	37	Cashier	
20	A.B.	31	Laborer	
21	M.D.	34	Homemaker	
22	M.M.E.	36	Homemaker	
23	M.A.E.	55	Homemaker	
24	L.D.	27	Medical Assistant	Penicillin, ampicillin, amoxicillin
25'	D.P.	35	Homemaker	
26	L.M.	34	Homemaker	
27	J.C.	20	Student	
28	E.P.	38	Boxspring maker	
29	A.G.	52	Homemaker	
30	J.W.	47	Unemployed	
31	M.H.	44	Unemployed	Penicillin, aspirin
32	N.D.	34	Student	
33	M.C.	46	Homemaker	
34	L.C.	18	Student	
35	S.S.	37	Homemaker	
36	P.W.	38	Homemaker	
37	E.W.	42	Homemaker	Hayfever
38	L.B.	57	Homemaker	
39	K.M.	34	Homemaker	
40	E.M.	53	Homemaker	

Project Number: 96-8342H

DuPont HLO # 713-96

E.I. du Pont de Nemours & Company - H-21936

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

PANELIST LIST

Panelist Number	Panelist Initials	Age	Occupation	Allergies
41	M.G.	39	Day care teacher	
42	S.V.	31	Homemaker	
43	J.H.	26	Typist	
44	B.A.	49	Homemaker	Penicillin
45	H.O.	20	Student	
46	D.G.	33	Homemaker	
47	D.R.	49	Homemaker	
48	P.D.	35	Teaching assistant	
49	A.T.	57	Bakery worker	
50	K.H.	26	Homemaker	
51	V.T.	37	Homemaker	Animals, dust, pollen
52	P.A.	35	Unemployed	
53	M.W.	67	Homemaker	
54	T.T.	31	Homemaker	Hayfever
55	J.N.	31	Printer	Penicillin, aspirin, tetanus toxoid
56	J.D.	31	Homemaker	
57	J.D.	33	Homemaker	
58	D.K.	36	Homemaker	Hayfever
59	M.B.	60	Retired	
60	J.Z.	62	Homemaker	
61	Y.H.	40	Homemaker	
62	C.R.	18	Student	
63	S.B.	29	Daycare worker	Animal hair, hayfever
64	H.R.	38	Unemployed	
65	C.R.	18	Student	Penicillin
66	P.G.	26	Homemaker	
67	C.R.	28	Homemaker	
68	W.C.	24	Student	
69	T.F.	21	Supermarket worker	
70	R.D.	26	Unemployed	Penicillin, aspirin, Darvocet, codeine
71	K.A.	26	Homemaker	Dust, grass, trees, pollen, smoke
72	E.L.	47	Day care teacher	
73	M.L.	39	Homemaker	
74	T.E.	24	Homemaker	
75	M.C.	50	Day care teacher	Penicillin
76	D.Y.	59	Upholsterer	
77	A.G.	65	Salesperson	
78	A.G.	64	Homemaker	
79	J.F.	42	Unemployed	
80	D.D.	58	Crossing guard	

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Modified Draize Repeated Insult Patch Test Study in Human Volunteers

PANELIST LIST

<u>Panelist Number</u>	<u>Panelist Initials</u>	<u>Age</u>	<u>Occupation</u>	<u>Allergies</u>
81	H.R.	18	Student	
82	K.B.	32	Homemaker	
83	D.R.	31	Homemaker	Sulfur
84	A.B.	70	Homemaker	
85	W.M.	30	Waitress	
86	S.M.	26	Hairdresser	
87	J.M.	45	Printer	
88	B.M.	45	Secretary	
89	C.J.	39	Homemaker	
90	A.N.	48	Processor	
91	C.C.	19	Student	
92	V.M.	31	Student	Hayfever
93	N.S.	37	Unemployed	
94	V.S.	24	Unemployed	
95	J.S.	35	Homemaker	Hayfever
96	R.S.	52	Unemployed	Penicillin
97	E.N.	52	Physical therapist	
98	D.H.	40	Secretary	Animal hair
99	J.H.	49	Machine operaor	
100	D.K.	39	Office worker	
101	K.N.	33	Accounts payable	
102	B.M.	48	Homemaker	Metals
103	V.F.	48	Welder	
104	L.T.	27	Homemaker	
105	E.G.	43	Homemaker	Antibiotics
106	M.C.	27	Laborer	Cats
107	R.F.	47	Congressional aide	
108	M.S.	38	Payroll clerk	Hayfever
109	R.P.	18	Unemployed	
110	E.D.	33	Hairdresser	
111	J.B.	28	Isurance adjuster	

Project Number: 96-834211

DuPont HLO # 713-96

E.I. du Pont de Nemours & Company - H-21936

Modified Draize Repeated Insult Patch Test Study in Human Volunteers

APPENDIX III
GRADING SCALE

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ConTox Limited - P.O. Box 368, Fort Washington, Pennsylvania 19034-0368

Company Sanitized. Does not contain TSCA CBI

Appendix IIIHuman Patch Test Studies Grading Scale

<u>Reading</u>	<u>Interpretation</u>
0	negative
±	suspicious
1+	slight erythema
2+	well defined erythema
3+	erythema with induration
4+	erythema with ulceration

DEFINITIONS*

Sensitization is a phenomenon which manifests itself by local effects on either skin or mucous membranes. It differs from primary irritation in that it may also involve tissues remote from the site of application. These reactions represent an allergy to a chemical which is not obtained on first contact, but requires a number of prior exposures for development.

Repeated patch applications of substances to both man and animals reveal that certain substances which, at a given concentration, do not produce primary irritation may elicit severe skin reactions after a number of exposures. Nevertheless, these reactions may not be considered incidents of sensitization since after 10-14 days of rest the skin recovers its original resistance to injury by the substance. For the lack of a better term such reactions have been called "skin fatigue". This latter term is a misnomer in that it does not imply a condition in which the skin has lost significant normal physiological function. This phenomenon consists of a subtle change in which the skin no longer exhibits its original refractoriness or resistance to the continued or repeated action of an agent.

* Draize, J.H. 1959. Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. In DERMAL TOXICITY, p. 46-53. Topeka, Kansas: Association of Food and Drug Officials of the United States.